OCT - 4 2000

K002962

Attachment 4

510(k) Summary

This 510(k) summary is submitted in accordance with the requirements in 21 CFR §807.92

Submitted by:	RADI Medical Systems AB Palmbladsgatan 10 SE-754 50 Uppsala, Sweden Phone:(+46) 18161000
Contact Person:	Mats Granlund
Date Prepared:	September 20, 2000
Proprietary Name:	PressureWire™ Sensor
Common Name:	Pressure Guide Wire
Classification Name:	Catheter Guide Wire (870.1330) Catheter Tip Pressure Transducer (870.2870)
Predicate Device:	PressureWire™ Sensor 510(k) # K983506

Description of the Device: The PressureWire™ Sensor is a 0.014" diameter, 183 or 300 cm long guidewire with a pressure sensor mounted three cm from the absolut tip and a detachable cable for connection to a blood pressure computer of the manufacturer's.

Intended Use of the Device: These devices have the same intended use as the predicate PressureWire™ Sensor. The PressureWire™ Sensor is intended for use in coronary and peripheral blood vessels to measure blood pressure during percutaneous procedures and to facilitate the placement of interventional devices.

Technical Characteristics: With exception of the lenght of the Guide Wire part, the subject device has the same technological characteristics as the predicate PressureWire™ Sensor.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 4 2000

Mr. Mats Granlund
Quality & Regulatory Affairs Manager
RADI Medical Systems AB
Palmbladsgatan 10
SE-754 50 Uppsala, Sweden

Re: K002962
Trade Name: PressureWire™ Sensor
Regulatory Class: II (two)
Product Code: 74 DQX
Dated: September 20, 2000
Received: September 22, 2000

Dear Mr. Granlund:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2

Indication for Use Statement

510(k) Number: K 002962

Device Name: PressureWire™ Sensor

Indications for Use: The PressureWire Sensor is intended for use in coronary and peripheral blood vessels to measure blood pressure during percutaneous procedures and to facilitate the placement of interventional devices.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K002962

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109)